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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,283	11/18/2003	David P. Jacobus	JACB-0053	6080
7590	01/12/2006		EXAMINER	
Walter C. Frank WOODCOCK WASHBURN LLP 46th Floor One Liberty Place Philadelphia, PA 19103			BALASUBRAMANIAN, VENKATARAMAN	
			ART UNIT	PAPER NUMBER
			1624	
DATE MAILED: 01/12/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/716,283

Applicant(s)

JACOBUS ET AL.

Examiner

Venkataraman Balasubramanian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-101 is/are pending in the application.
- 4a) Of the above claim(s) 91-101 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/4/04, 5/17/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-101 are pending.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-90, namely biguanidine along with a species election in paper dated 10/14/2005, is acknowledged. Claims 1-90 will be examined to the extent they embrace the elected subject matter. Claims 91-101 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The traversal is on the ground(s) that it is the method of use claims, as matter of right should be rejoined once the elected subject matter namely the biguanidine compounds were found allowable.

First, examiner will examine the elected subject matter and if it is found to be allowable then will rejoin the method of use claim and apply any applicable rejections.

The restriction requirement is still deemed proper and is made FINAL.

Claims 1-90 are now under examination.

Information Disclosure Statement

References cited in the Information Disclosure Statements dated 3/4/2004 & 5/17/2004, are made of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply. Any claim not specifically rejected is rejected as being dependent on a rejected claim and shares the same indefiniteness.

1. In claim 1, recitation of "R^{3a} and R^{3b} taken together form a spiroalkyl" renders claim 1 and claim 90, render these claims and the dependent claims 2- indefinite and vague as it is not clear how a spiroalkyl would be formed from these two groups.
2. In claim 89, recitation of "sulfonamide or sulfone" renders claim 89 indefinite for more than reason. First of all, there appears to be no antecedent basis for sulfonamide and sulfone in claim 87 or claim 1. Secondly, it is not clear whether these terms are generic or specific. In addition, a sulfone is a divalent radical and hence needs an additional group to meet the valence requirement and such a groups as recited in claim 89 remains unknown.

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3. Recitation of "compounds" in process claim 90 renders this claim indefinite, as it is not clear whether it is a process for making a compound or a mixture of compounds. In addition, the phrase "under conditions sufficient to provide" is vague and unclear. This claim is a process claim and these conditions are critical to the process they should be clearly stated.
4. Recitation of "at least one compound according to claim 1" in claims 17 and 18 renders these claims indefinite as it is not clear what is intended. As recited, it implies that the composition should have at least one compound of claim 1 as active ingredient and another active ingredient. Replacement of the phrase "at least one" with "one or more" is suggested.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 90 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for various non-nucleophilic functional groups as substituents for R₁ group, "does not reasonably provide enablement for SH, NH, NH₂ or for labile NHSO₂H group as recited for compound of formula I embraced claim 90. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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In evaluating the enablement question, following factors are considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims; and 7) the quantity of experimentation needed.

1. The nature of the invention and the state of the prior art:

The invention is drawn to a process of making compound of formula I shown in claim 90 wherein a nucleophilic attack of amino group of compound II on cyano group of compound III leads to compound of formula I of claim 90. In addition to various non-nucleophilic functional groups, claim 90 also permits SH, NH, NH₂ as well as labile NHSO₂H substituents on choices of R₁ group, all of which are capable of attacking the cyano group. Specification is not adequately enabled as to how to make compounds of formula I shown in claim 90 wherein the above said reactive functional groups which are also capable of reacting with cyano group. In addition, specification is not adequately enabled for compound of formula I with the substituent NHSO₂H on the various choices of R group embraced therein.

Specification offers no teachings or suggestion as to how to make such compounds in presence of these reactive groups.

2. The predictability or lack thereof in the art:

The process of making biguanidine as applied to the above-mentioned compounds claimed by the applicant is not an art-recognized process and hence

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there should be adequate enabling disclosure in the specification with working example(s) to make these claimed compounds.

3. The amount of direction or guidance present:

Examples illustrated in the experimental section or written description offer no guidance or teachings as to how make these compounds when reactive substituents or chemically incompatible substituents are present in the starting material.

5. The presence or absence of working examples:

Although examples in Specification show enablement for number of compounds, they are limited to compounds with no reactive functionality. There are no representative examples showing the viability of the process for the various reactive substituents mentioned above embraced in the instant claims.

6. The breadth of the claims:

Specification has no support, as noted above, for all compounds generically embraced in the claim language would lead to desired compound of formula I with said reactive groups and there is also no valid chemical reasoning for one trained in the art to expect that all these functional groups would be inert toward the cyano group in the recited process of making the compound of formula I.

7. The quantity of experimentation needed:

The quantity of experimentation needed would be an undue burden on skilled art in the chemical art since there is inadequate guidance given to the skilled artisan for the many reasons stated above. Even with the undue burden of

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experimentation, there is no guarantee that one would get the product of desired structure, namely compound of formula shown in claim 1 in view of the general reactive of above said groups.

Thus, factors such as "sufficient working examples", the "level of skill in the art and predictability, etc. have been demonstrated to be sufficiently lacking in the case for the instant claims.

Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM.

The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair->

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Venkataraman Balasubramanian

1/5/2006